



ADALIMUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about adalimumab (Humira™). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is adalimumab and how does it work?

Adalimumab is a powerful drug that has been specially designed to mimic normal human molecules, and for this reason it is classed as a 'biological' drug. It reduces inflammation by inhibiting the activity of a chemical 'cytokine' in the body called 'tumour necrosis factor alpha' (TNF-alpha).

Which conditions are treated with adalimumab?

Adalimumab is used to treat psoriasis, psoriatic arthritis, and several other inflammatory conditions such as rheumatoid arthritis and Crohn's disease.

Why have I been selected for treatment with adalimumab?

The use of adalimumab is reserved for patients with severe psoriasis who either have not responded to standard treatments, have not been able to tolerate standard treatments or who have a contraindication to standard treatments such as methotrexate, ciclosporin or ultraviolet light therapy.

How long will I need to take adalimumab before it has an effect?

Adalimumab does not work immediately and it may be 3-12 weeks before you notice any benefit. In clinical trials, about 68% of patients achieved a good response (as indicated by 75% improvement in the score of their disease severity).

How do I take adalimumab?

Adalimumab is presented as a pre-filled syringe or in a pre-filled pen device. The pen device automatically injects the drug under the skin. A nurse or doctor will demonstrate how to use the pen; details are also given in the package insert. It must be stored in a refrigerator (at 2-8°C). Travelling with adalimumab, or transporting your treatment, requires a cool box or cool bag with icepacks to maintain these temperatures. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with sharps bins so that you can dispose of your syringes and needles safely.

What dose should I take?

The recommended dosage schedule of adalimumab for an adult patient with psoriasis is an initial loading dose of 80 mg, followed by 40 mg every other week for four months starting one week after the initial dose. If the response at four months is deemed adequate by your dermatologist, treatment would then normally be continued to maintain improvement. If treatment is stopped, your psoriasis will probably recur but this is unlikely to happen in the first month.

What are the possible side effects of adalimumab?

Mild

- *Reactions at the injection sites.* These are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your dermatologist.
- *Upper respiratory infections,* for example, sinus infections.
- *Headaches, rash, nausea.*

Potentially severe

- *Serious infections.* Adalimumab may decrease your ability to fight infection. Inform your doctor of any current or past infection (particularly tuberculosis), or if you are prone to infections such as cold sores or cystitis. Also tell your doctor if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS), or viral hepatitis. Try to avoid close contact with anyone with a bad cold, influenza or chest infections, and wash your

hands frequently when taking this medication. Avoid dairy foods that are not pasteurised, Camembert, Brie and blue cheeses, pâté or eggs, meat or poultry that are not adequately cooked and thus pose a risk of salmonella infection. Contact your doctor if you get an infection, or any symptom or sign of an infection, including: fever, lethargy, cough, influenza-like symptoms, warm, burning on passing urine, dental problems, red or painful skin, and open sores on your body. Your dermatologist may suggest discontinuing adalimumab temporarily.

- *Nervous system diseases.* There have been rare cases of adalimumab affecting the nervous system. Symptoms of this include: numbness or tingling; problems with vision; weakness in the arms and/or legs; and dizziness. Tell your doctor if you have ever had a nervous system complaint, such as multiple sclerosis, Guillain-Barré syndrome or seizures.
- *Blood problems.* Some patients taking adalimumab may fail to produce enough of the blood cells that help to fight infections or to stop bleeding. If you develop a fever that doesn't go away, bruise or bleed very easily, or look very pale, contact your doctor.
- *Heart problems.* You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on adalimumab, or may want to monitor you more closely. While on treatment you should inform your dermatologist if you develop swelling of feet, shortness of breath on exertion or on lying flat.
- *Allergic reactions.* Some patients have had allergic reactions to adalimumab. If you develop a severe rash, a swollen face, or difficulty with breathing while taking adalimumab, you must go to a hospital A&E department immediately and make sure that your dermatologist is informed. If the reaction is severe, such as difficulty breathing, dial 999 and go to A&E by ambulance.
- *Lupus-like reactions.* Some people taking adalimumab have developed symptoms (such as rash and joint pains) that resemble lupus erythematosus, and these usually go away when you stop taking adalimumab.
- *Cancers.* Many drugs that decrease the activity of the immune system can increase the chance of getting a cancer: the risk cannot be quantified, but is low. There have been rare reports of lymphoma (a tumour of the lymph glands) in patients taking adalimumab. Non-melanoma skin cancers have occurred in patients taking adalimumab and are more common if you have received a lot of ultraviolet light therapy. Your dermatologist should be consulted if you have any concerns about new skin lesions.

Before you start taking adalimumab, your dermatologist will go through a checklist for the following:

- *Tuberculosis*, or close contact with someone who has had it. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. You will need to be examined for tuberculosis and have a skin or blood test.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- *Numbness or tingling* or a disease that affects your nervous system like multiple sclerosis.
- *Congestive heart failure*, or if you are already being treated for it.
- If you are scheduled to have *major surgery*.
- If you are scheduled to have *any type of vaccination*.
- *Latex allergy*; latex is present in the needle cover only in the prefilled syringe preparation not in the pen.

You should make sure that you have any regular tests (e.g. with cervical smears and mammograms) to screen for common cancers if you are at the age when these are recommended.

What will happen if I need an operation or dental surgery?

Adalimumab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking adalimumab.

How will I be monitored for the side effects of adalimumab treatment?

You will probably have a chest X-ray and blood tests before treatment starts; and blood checks need only be done 3 months after commencing adalimumab, and then every 6 months. Monitoring your response and looking out for side effects will take place at regular clinic visits.

The BAD Biologic Interventions Register (BADBIR)

Because adalimumab treatment for psoriasis is relatively new, you will be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use adalimumab and similar drugs. No information will be passed to the register without your informed consent.

Can I have immunisations (vaccinations) whilst on adalimumab?

Patients on adalimumab should not be given any of the 'live' vaccines such as those for polio, rubella (German measles) and yellow fever, although 'inactivated' vaccines are safe. If you require immunisation with a live vaccine, adalimumab should be stopped for at least 6 months before and until 2 weeks after the vaccination. Pneumovax and annual influenza vaccinations are safe and are recommended; however, the new nasal flu vaccination is live and should not be given with adalimumab (see Patient Information Leaflet on [Immunisations](#)).

Does adalimumab affect pregnancy?

Adalimumab has not been studied in pregnant women or nursing mothers, and so its effects on unborn children or babies who are being breast fed are unknown. You should tell your doctor if you are pregnant or become pregnant, and should discuss with your doctor any plan to become pregnant. Otherwise use appropriate contraception.

Can I travel abroad while taking adalimumab?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on the length of your travel plans, you may need a cool box to take the medication with you. Depending on where you are travelling, precautions may need to be taken against infections. Your dermatologist may be able to advise you on this.

May I drink alcohol while I am taking adalimumab?

There is no known interaction between alcohol and adalimumab.

Can I take other medicines at the same time as adalimumab?

Most medicines are safe to take with adalimumab. However, it is important that your GP and other doctors are aware that you are taking it if any new drug is prescribed. Your GP and dermatologist should be aware of all your medications, including over-the-counter ones, and supplements, including herbal medicines. Methotrexate can be taken along with adalimumab. However, you should not take other immunosuppressives (medicines which suppress the immune system) while you are on adalimumab.

Can I sunbathe?

Sun beds and sunbathing should be avoided to reduce the risk of skin cancer.

Where can I find out more about adalimumab?

This information sheet does not list all of the side effects of adalimumab. If you wish to find out more about adalimumab, or if you are worried about your treatment, you should speak to your doctor, specialist nurse or pharmacist.

For fuller details, look at the drug information sheet which comes as an insert with your prescription for adalimumab.

Or visit the website <http://www.humira.com/>

The Psoriasis Association

<https://www.psoriasis-association.org.uk/>

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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